REMARKS

Claims 1-14 and 16-25 are currently pending in the application. Claims 1, 17, 22, and 23 are in independent form.

Applicant expresses his gratitude for courtesies extended by the Examiner during a personal interview conducted with Applicant's representative, Kenneth I. Kohn, that occurred on November 17, 2009. During the interview, proposed amendments to the claims were discussed and are included herein.

Claim 1 has been amended to positively set forth the limitations of the hub and stop surface as suggested in the interview. Claims 22 and 23 have been amended to define the length of the device rather than it's relative position to a target as suggested in the interview. Support for this amendment can be found in paragraph [0018]. No new matter has been added. **Applicant emphasizes that no one in the prior art is using a catheter with as small of a diameter of a single tube as defined in claim 1, and absolutely no one is using a catheter with the diameter of claim 2.**

U.S. Patent No. 7,270,650 to Morris, et al. was mentioned in the interview. Morris, et al. has a priority date of April 23, 2002, whereas the present application has a priority date of March 12, 2002. Therefore, Morris, et al. would not be considered prior art to the present application. Nevertheless, Morris, et al. does not disclose any dimensions of the diameter of the catheter therein, and therefore certainly does not disclose any criticality to the dimensions of the diameter. Furthermore, Morris, et al. does not disclose a catheter that includes a hub and stop surface as part of its integral structure as in the present invention, but rather a separate anchor device that anchors the catheter.

Claims 1-5 and 24-28 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 6,045,532 to Eggers, et al. Specifically, the Office Action holds that Eggers, et al. discloses a neurosurgical catheter with an external diameter not more than 0.5 mm and that has a stop at the proximal end. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Eggers, et al., as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

Eggers, et al. includes a fluid path for dispensing a conductive fluid to the region of the brain to be ablated in addition to the electrodes, shown in detail in Figure 2. In other words, Eggers, et al. discloses multiple tubes, whereas the present invention is directed to a single fine tube. The present invention does not include multiple fluid tubes and an electrode as described in Eggers, et al., and any fluid that might be delivered is delivered itself through the single fine tube. Claim 1 has been amended to reflect this point. Furthermore, Eggers, et al. does not disclose a catheter with any kind of stop. The stop surface of the hub is important in order to set the depth of insertion of the fine tube in the brain parenchyma. Without

the hub and stop surface, there is a risk that the fine tube would be inserted too far and damage brain tissue.

Therefore, since Eggers, et al. does not disclose a single fine tube catheter or a stop with a hub as set forth in the presently pending independent claims, the claims are patentable over Eggers, et al. and reconsideration of the rejection is respectfully requested.

Claims 1-6, 17, and 22-28 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 7,033,326 to Pianca, et al. Specifically, the Office Action holds that Pianca, et al. discloses a neurosurgical catheter with an external diameter not more than 0.5 mm that is inserted and connected to a guide tube as well as a method of using the device. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Pianca, et al., as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

Pianca, et al. discloses an electrode for brain implantation, not a catheter as in the present invention that is a fine tube and can be used to deliver drugs. A tube by definition is a structure including a hollow recess. The electrode of Pianca, et al. is not a fine tube. The "electrode tube 136" referred to by the Office Action is part of the electrode device and is not a catheter. Just a Pianca, et al. does not disclose a catheter, Pianca, et al. does not disclose the other features of the catheter of the present invention such as the stop surface and the hub.

Therefore, since Pianca, et al. does not disclose a catheter having a fine tube as set forth in the presently pending independent claims, the claims are patentable over Pianca, et al. and reconsideration of the rejection is respectfully requested.

Claims 1 and 17-22 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 6,609,020 to Gill. Specifically, the Office Action holds that Gill discloses a neurosurgical catheter with an external diameter less than 1 mm and a guide tube with a dome, a channel, and screws. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Gill, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

Gill (an earlier patent by the inventor of the present invention) discloses placing a 1 mm diameter electrode in the subthalamic nucleus is technically demanding in column 7, but does not disclose any diameter with respect to the guide tube itself. Furthermore, Gill teaches away from a diameter of a guide wire less than 1 mm because it is likely to be deflected from its target by resistance in the tissues and that a larger diameter guide wire is preferred (column 7, lines 36-49). Gill does not disclose a catheter with a fine tube having an external diameter of 1 mm or less. Furthermore, Gill does not disclose a catheter having a stop surface or hub as required in the presently pending claims.

Therefore, since Gill does not disclose a catheter with an external diameter less than 1 mm and the stop surface and hub as set forth in the presently pending independent claims, the claims are patentable over Gill and reconsideration of the rejection is respectfully requested.

Claims 1-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gill and further in view of Eggers, et al. and U.S. Patent No. 6,719,727 to Brimhall, et al. Specifically, the Office Action holds that Gill discloses the claimed invention except

for the size of the catheter or insertion device having an outer diameter not more than 0.5 mm. Gill also fails to disclose a hub that connects two tubes together as well as the hub having flanges that can be attached to the skull. The Office Action holds that Eggers, et al. discloses the size of the neurosurgical catheter being around 0.5 mm. The Office Action holds that Brimhall, et al. discloses a winged catheter hub that can be attached to the skull because of the stiffening members that are located within the hub and have a countersunk hole as well as the hub being used as a linking passage and connects two tubes with different diameters. Therefore, the Office Action holds that it would have been obvious for one skilled in the art to combine the device of Gill with the teachings of Eggers, et al. and Brimhall, et al. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Gill, Eggers, et al., and Brimhall, et al. is respectfully requested.

> "Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).
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> "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP Section 2143.
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> "The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 83 UDPQ2d 1385, 1395 (2007) and MPEP Section 2143.

As described above, neither Gill nor Eggers, et al. disclose each and every limitation of the presently pending claims, i.e. the catheter diameter being 1 mm or less and the stop surface and hub structure.

Brimhall, et al. discloses an intravascular catheter assembly that has a catheter adapter 24 which links a first tube 21 for insertion into a vein with a larger diameter tube 25 for connection to a fluid supply (e.g. a drip). Intravascular catheter assemblies of this type have been widely used for many years. While the Brimhall, et al. device may look similar upon first glance to the catheter of the present invention, they are quite different. Brimhall, et al. does not make up for the deficiencies of Gill and Eggers, et al. Furthermore, one skilled in the art would not look to Brimhall, et al. in order to modify Gill and Eggers, et al. because an intravascular catheter is not considered suitable for use in neurosurgery.

Brimhall, et al. does not disclose a tube of less than 1 mm in diameter and only discloses intravascular catheters (i.e. not catheters for insertion into the brain parenchyma). Thus, the Brimhall, et al. device is designed and used for a completely different purpose than the neurosurgical catheter of the present invention. During insertion into a vein, the catheter tube 21 of the Brimhall, et al. device is stiffened by a needle. The needle and tube together penetrate the skin allowing the tube to be inserted into the selected vein. The direction of insertion into the body is controlled manually by the clinician and with wings 26 provide the clinician with a better grip of the device thereby making insertion into the vein easier (see paragraphs 3 and 39-40 of Brimhall, et al.). The clinician would typically almost fully insert the catheter 21 into the vein, but would typically leave a small proximal length of the catheter 21 exposed before securing the wings to the patient's skin (i.e. using tape or sutures).

Brimhall, et al. further does not disclose a stop surface as in the present invention. While there is a step change in diameter between the tube 21 and catheter adapter 24, the device would not be used as a stop surface. In particular, the Brimhall device is inserted into the body at a shallow angle, and there is no reference surface against which the catheter 24 adapter could abut. The catheter adapter of Brimhall, et al. therefore does not set the depth of catheter insertion into the vein by acting as a stop surface; instead, the depth of insertion is manually controlled by the clinician.

Thus, neither Gill, Eggers, et al., or Brimhall, et al. disclose each and every limitation of the present invention.

Furthermore, the present invention provides unexpected results of precise targeting while delivering drugs and reduced brain trauma due to the size of the fine tube and the function of the stop surface. A declaration has previously been submitted to support these results.

The goal of a surgeon using a neurosurgical catheter is to minimize reflux or backflow of drug, avoid tearing tissue upon insertion of the catheter, and controlled perfusion of the drug at a specific target within the brain. Before the present invention, this was not possible. In any other catheter in the prior art that is used for drug delivery to the brain, the drug follows the path of least resistance upon exiting the tip of the catheter. In general, the drug permeates a broad area of tissue, i.e. a nonspecific area of tissue, which can cause damage to healthy brain tissue. Furthermore, prior art catheters have larger diameter tubes which cause tearing of brain tissue, adding additional damage.

See enclosed reference "Reflux-free cannula for convection-enhanced high-speed delivery of therapeutic agents" by Krauze, et al., J Neurosurg 103:923-929, 2005. This reference describes the problems of current cannulas with reflux and low flow rates due to large diameters. Different size diameters were analyzed in the experiments. Figure 1(a) shows the amount of reflux with each diameter of catheter. Larger diameters experienced more reflux. The results were that smaller diameters allowed for higher flow rates.

The present invention overcomes these problems in the art by using a fine tube with an external diameter of not more than 1.0 mm, and even smaller in some embodiments (0.7 mm, 0.5 mm). By using such a small tube, point delivery of a drug to specific brain tissue can be accomplished without tearing of tissue upon insertion. More importantly, deep brain tissue can be targeted with the present invention. By including the stop surface, the tip of the catheter is maintained at the correct position in order to delivery drug to only the desired target tissue. The stop also prevents over-penetration and the subsequent need for retraction of the catheter tip during the implantation procedure. In particular, it has been found that over-penetration of the catheter into brain tissue by only 1 mm causes a microcavity to form in the brain tissue. Pumping an infusate down the catheter then causes this cavity to expand, which degrades the infusate distribution profile within the brain tissue thereby reducing treatment efficacy. Having the stop on the catheter prevents such over-penetration.

See paragraph [0036] in the specification:

As explained above, insertion of a catheter into particularly sensitive regions of the brain leads to trauma on insertion which surgeons wish to minimise. The finer the catheter the less trauma the brain experiences. However, since the accuracy of insertion is crucially important, and since these particularly sensitive areas of the

brain are a considerable distance from the skull surface, larger diameter catheters have been considered to be necessary in order to accurately place the distal end of the catheter. However, the present invention allows much finer catheters to be used.

See also paragraph [0001]:

The present invention relates to apparatus for use in neurosurgery, and to a method of positioning neurosurgical apparatus. The apparatus and method are particularly useful in stereotactically targeting treatment of abnormalities of brain function, and for the infusion of therapeutic agents directly into the brain parenchyma. This would be particularly useful when a therapeutic agent given systemically will have widespread unwanted side effects which would be avoided by confining the delivery to the malfunctioning or damaged brain tissue.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB

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I hereby certify that this correspondence is being electronically filed with the United States Patent & Trademark Office on the above date.

/Natalie Zemgulis/
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